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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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COOLEY GODWARD LLP
ATTN: PATENT GROUP
11951 FREEDOM DRIVE, SUITE 1700
ONE FREEDOM SQUARE- RESTON TOWN CENTER
RESTON, VA 20190-5061

EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,135

Applicant(s)

HITT ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/30/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

300

Art Unit: 1631

DETAILED ACTION

Claims 1-24 are currently pending.

Priority

The benefit of priority to US Provisional Application 60/398,831 (29 July 2002) is hereby denied. The Provisional Application fails to provide support for computing a location of a centroid in n-dimensional space based upon the steps of the instant claims.

Information Disclosure Statement

The Information Disclosure Statement filed 13 November 2003 has been considered. A signed copy of PTO Form 1449 is included with this Office Action.

Claim Objections

Claim 15 is objected to because of the following informalities: There is a spelling error at line 9. The word "form" should be corrected to read "from". Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-24 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The methods of claims 1-24 are not supported by a specific asserted utility or a well-established utility. The claimed methods are directed to initializing a control model for a bioassay process by obtaining data from an aliquot of a mixture and performing a bioassay and

Art Unit: 1631

computing a location of a centroid in n-dimensional space that somehow defines the control model. However, there is no specific utility set forth such that this result is immediately useful. The specification states that the method is performed to obtain a control model (page 4, paragraph [0020]). This does not constitute a specific utility, as set forth under 35 USC 101. Applicant is reminded that a "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. In the instant case, computing a centroid to define a control model, without such knowledge as to what to use the control model for, does not constitute a specific utility.

Claims 1-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1631

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “a method of initializing a control model”. It is unclear what “initializing” means. Does this mean a method of configuring a control mode, a method of starting a control model or a method of preparing a control model? Clarification is requested.

Claims 1 and 12 recite “the location of the centroid in n-dimensional space defining the control model” and “the centroid defining the predetermined model”, respectively. It is unclear what about the control model the n-dimensional space defines. What does the centroid represent such that a control model is defined? Clarification is requested.

Claim 8 recites, “obtaining a distance based on a plotted location”. It is unclear what distance is being obtained. The distance from what to what? What does the distance represent? Clarification is requested.

Claim 11 recites, “create the predetermined control model”. There is insufficient antecedent basis in the claim for “the predetermined control model”. Clarification is requested.

Claim 15 recites “a method of testing a bioassay process against a control”. There is no step of testing a bioassay against a control in the claim. Rather, the final step is determining a distance. Clarification is requested.

Art Unit: 1631

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-13, 15-18, 20, 21, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0004402 (Hitt et al.) ('402 herein).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claims are drawn to a method of initializing a control model for a bioassay and a method of testing a bioassay process against a control. The instant claims require the computing of a location of a centroid in n-dimensional space to define a control.

'402 teaches an invention for determining a biological state through the discovery and analysis of hidden or non-obvious, discriminatory biological data patterns (abstract). In particular, in regard to claims 1, 3, 8, 15, 18, and 21 '402 teaches obtaining data from various biological data, including clinical data, health data, biological fluids etc. (page 2, paragraph 0015). Further, '402 teaches obtaining the data and determining vectors associated with the data

Art Unit: 1631

such that optimal clusters may be generated that form a cluster map. The map comprises rules that define the clusters as being located at the centroid and that the dimension of each cluster is fixed prior to generating the map (page 3, paragraph 0021 and page 6, paragraph 0049).

In regard to claims 2 and 20, various aliquots are used (see page 7, paragraph 0064).

In regard to claim 4, the molecules include peptides (page 4, paragraph 0032).

In regard to claims 6, 9, 16, and 23 the bioassay is a SELDI process (page 4, paragraph 0032).

In regard to claims 7, 10, 17, and 24 the method can include using a chip (page 3, paragraph 0019).

In regard to claim 11, '402 teaches that the learning data set is data formed from biological samples from which the biological state of interest is provided for pattern discovery (page 3, paragraph 0018).

In regard to claims 12 and 13, '402 teaches that data are determined to be within or outside of the cluster (page 3, paragraph 0021). If the data are within or without, this determines the classification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1631

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 8, 15, 19, 21, and 22 are rejected under 35 U.S.C. 103(a) as being obvious over US 2003/0004402 (Hitt et al.) ('402 herein) for the reasons set forth above, in view of Petricoin et al. (The Lancet (2002) Vol. 359, pages 572-577 ; PTO 1449 Reference Number 21).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of

Art Unit: 1631

invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

'402 does teach the embodiments of claims 1, 8, 15, and 21, as set forth above. '402 does not teach molecular weight specifics or the mass to charge ratio as set forth in claims 5, 14, 19, and 22. However, Petricoin et al. teach that it is routine in SELDI-TOF to assess the mass to charge range and to use proteins within a mass of 0-20,000 Da (page 573, column 2, Proteomic analysis section).

It would have been prima-facie obvious to one of ordinary skill in the art at the time of the invention to have used the SELDI-TOF parameters of Petricoin et al. in the methods of '402. One would have been motivated to do so because Petricoin et al. state that it is routine to use such parameters (page 573, column 2).

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

September 30, 2005
Lori A. Clow, Ph.D.
Art Unit, 1631
Lori A. Clow

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
10/3/05